DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-280/S-040

Pharmacia & Upjohn
Attention: Cynthia Blanchard
Senior Regulatory Manager
7000 Portage Road
Kalamazoo, Michigan 49001

Dear Ms. Blanchard:

Please refer to your supplemental new drug application dated March 29, 2002, received April 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Genotropin (somatropin [rDNA origin] for injection).

We acknowledge receipt of your submissions dated May 20, 21, 31, July 16 and 19, November 20, October 16, December 13, 2002, January 9, February 18, and March 4, 2003.

Your submission of February 18, 2003, constituted a complete response to our January 23, 2003, action letter.

This supplemental new drug application provides for a new needle-free injection system (Genotropin Zip Tip) for use with Genotropin 5.8 mg and 13.8 mg dual chamber cartridges.

We completed our review of this application, as amended and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, submitted February 18, 2003, patient package insert, submitted March 4, 2003, carton label, ampoule carton label, connector carton label, and Genotropin ZipTip carton label, submitted March 29, 2002.)

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-280/S-040." **Approval of this submission by FDA is not required before the labeling is used.**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Monika Johnson, Regulatory Project Manager, at (301) 827-9087.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
(HFD-510)
Office of New Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures: Patient Instructions for Use
Package Insert
Genotropin ZipTip carton
Connector carton
Ampoule carton

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Monika Johnson

5/12/03 11:33:35 AM